Group Art Unit: Not yet assigned

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

CAVALERI et al.

Serial No.: Not yet assigned

Filed: Submitted herewith

For: METHODS OF ADMINISTERING

DALBAVANCIN FOR TREATMENT

OF SKIN AND SOFT TISSUE

INFECTIONS

## INFORMATION DISCLOSURE STATEMENT

MAIL STOP PATENT APPLICATION Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97–1.98, information relating to the above–identified application is hereby disclosed. The accompanying Form PTO–1449 provides a listing of documents that may be relevant to the subject application.

It is requested that the Examiner fully consider the art cited in the accompanying Form 1449, initial the left-most column of the form adjacent each cited reference, and return a copy for Applicants' records. It is further requested that the art be cited on the cover of any patent issuing from the subject application.

CERTIFICATE OF MAILING (37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Commissioner for Patents, PO Box 1450 Alexandria, VA 22313-1450.

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April 16, 2004

Date of Deposit

Anthia B. Pacheco

In accordance with §1.97(b), this Information Disclosure Statement is being filed within three months of the filing date of the above-identified application, and therefore no fee is required.

In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO–1449 are not enclosed herewith because they were previously cited by or submitted to the Patent and Trademark Office in one or more of the prior U.S. Application Serial No. 10/714,261, filed November 14, 2003, which claims the benefit of U.S. Provisional Patent Application Serial Nos. 60/427,654, filed November 18, 2002, 60/485,694, filed July 8, 2003, 60/495,048, filed August 13, 2003, and 60/496,483, filed August 19, 2003, by CAVALERI, et al. for which a claim for priority under 35 U.S.C. §120 has been made in the instant application. Accordingly, Applicants will provide duplicate copies in respect of the present case only if the Examiner so desires.

This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made. Nor does this statement constitute an admission by Applicants or Applicants' agent that the information provided herein is necessarily prior art to Applicants' invention. Moreover, Applicants reserve the right to establish the patentability of the claimed invention over any of the listed documents should they be applied there—against as references. Please charge any deficiency or credit any overpayment to Deposit Account No. 50-2862.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: April 16, 2004

Diane K. Wong

Reg. No. 54,550

Attorneys for Applicant

DKW/kmg

O'Melveny & Myers LLP 114 Pacifica, Suite 100 Irvine, CA 92618-3315 (949) 737-2900

## Form PTO-1449

## INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket No. 892,280-147

Application No.: . Not Yet Assigned

Applicant: CAVALERI et al.

Filing Date: Submitted herewith

Group Art Unit: Not Yet Assigned

Mailing Date: April 16, 2004

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	03/25/1980	4,195,079	Celmer et al.			
	2.	12/16/1980	4,239,751	Coronelli et al.			
	3.	09/17/1985	4,542,018	Borghi et al.			
	4.	04/28/1987	4,661,470	Malabarba et al.			
	5.	11/01/1988	4,782,042	Selva et al.			
	6.	09/19/1989	4,868,171	Selva et al.			
	7	11/21/1989	4,882,313	Sitrin			
	8.	04/03/1990	4,914,187	Malabarba et al.			
	9.	06/19/1990	4,935,238	Selva et al.			
-	10.	09/04/1990	4,954,483	Malabarba et al.			
	11.	07/09/1991	5,030,619	Hector			
	12.	11/12/1991	5,064,811	Borghi et al.			***
	13.	02/25/1997	5,606,036	Hermann et al.			
	14.	05/12/1998	5,750,509	Malabarba et al.			
	15.	12/01/1998	5,843,679	Selva et al.			-
	16.	03/16/1999	5,882,900	Rizzo et al.			
	17.	04/06/1999	5,891,869	Lociuro et al.			2
	18.	07/20/1999	5,925,550	Lancini et al.			
	19.	08/10/1999	5,935,238	Talcott et al.			
	20.	12/28/1999	6,008,225	Lociuro et al.			
	21.	11/07/2000	6,143,739	Lociuro et al.			
	22.	04/17/2001	6,218,505	Panzone et al.			
	23.	05/07/2002	6,384,013	Burkhardt et al.			···

**EXAMINER:** 

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Form PTO-1449

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### FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	24.	02/16/1983	EP 0 071 970	Europe			
· · · · · · · · · · · · · · · · · · ·	25.	11/30/1983	EP 0 095 154	Europe			
	26.	04/16/1986	EP 0 177 882	Europe			
	27.	12/10/1986	EP 0 204 179	Europe			
	28.	07/08/1987	EP 0 228 015	Europe			
	29.	10/14/1987	EP 0 240 609	Europe			
	30.	03/16/1988	EP 0 259 781	Europe			
	31.	02/01/1989	EP 0 301 785	Europe			
	32.	05/24/1989	EP 0 316 712	Europe		Ψ	
	33.	07/04/1990	EP 0 376 041	Europe			
	34.	02/03/1993	EP 0 525 499	Europe			
	35.	10/15/1997	EP 0 801 075	Europe			
	36.	07/28/1999	EP 0 931 834	Europe			
	37.	12/21/1983	GB 2 121 401	Great Britain			
	38.	02/15/1984	GB 2 142 234	Great Britain			
	39.	02/01/1989	JP 1050900	Japan			Abstract
	40.	04/21/1988	WO 88/02755	WIPO			
	41.	10/04/1990	WO 90/11300	WIPO			

## OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Initials	No.	
	42.	Abramson, M.A. and Sexton, D.J. (1999). "Nosocomial Methicillin-Resistant and Methicillin-Susceptible Staphylococcus Aureus Primary Bacteremia: At What Costs?" Infect. Control Hosp. Epidemiol. 20(6): 408-411.
	43.	Adamczyk, M. et al. (1999). "Investigations Into Self-Association of Vancomycin Covalent Dimers Using Surface Plasmon Resonance Technology," <i>Bioorganic &amp; Medicinal Chemistry Letters</i> 9:2437-2440.

**EXAMINER:** 

Examiner Ref.

DATE CONSIDERED:

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Form P10-1449		Docket No. 892,280-147	Application No.: Not Yet Assigned	
	ION DISCLOSURE CITATION I AN APPLICATION	Applicant: CAVALERI et al.		
a	Use several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned	
		Mailing Date: April 16, 2004		
		·		
44.	Ahrendt, K.A. et al. (2003). "Identifica Studies of a Synthetic Vancomycin Ar 1686.	ation of Potent and Broad-Spectr nalogue," <i>Bioorganic &amp; Medicin</i>	rum Antibiotics from SAR al Chemistry Letters 13:1683-	
45.	Allen, N.E. and Nicas, T.I. (2003). "M Antibiotics," FEMS Microbiology Rev		cin and Related Glycopeptide	
46.	Anderegg, T.R. et al. (2003). "Initial of Dalbavancin (BI397), an Investigation <i>Microbiol.</i> 41(6): 2795-2796.	Quality Control Evaluations for a land al Glycopeptide with Potent Gra	Susceptibility Testing of am-Positive Activity," J. Clin.	
47.	Anderegg, T.R. et al. (2003). "Multice 397), An Investigational Glycopeptide No. A-090, one page.	nter Quality Control Evaluation with Potent Gram-Positive Acti	Results for Dalbavancin (BI vity," ASM May 2003, Poster	
48.	Arimoto, H. et al. (1999). "Multi-Valent Polymer of Vancomycin: Enhanced Antibacterial Activity Against VRE," Chem. Commun. 1999:1361-1362.			
49.	Arimoto, H. et al. (2001). "Affinity of a Vancomycin Polymer with Bacterial Surface Models," Tetrahedron Letters 42:3347-3350.			
50.	Arioli, V. et al. (1976). "Gardimycin, A New Antibiotic From Actinoplanes: III. Biological Properties," Journal of Antibiotics 29(5):511-515.			
51.	Arthur, M. and Courvalin, P. (1993). "Genetics and Mechanisms of Glycopeptide Resistance in Enterococci," Antimicrobial Agents and Chemotherapy 37(8):1563-1571.			
52.	Author unknown. (2001). "Dalbavanci <a href="http://www.qxhealth.com/news_archiseptember-8">http://www.qxhealth.com/news_archiseptember-8</a> , 2003, one page.	n tested for soft tissue infections ieve/cfml/search_details.cfm?su	s," located at m_ID=8777> last visited on	
53.	Author unknown. (2000). "Molecule of http://www.prous.com/mom/nov_00/	of the Month V-Glycopeptide," lemon.html> last visited on Augu	ocated at state 27, 2002, two pages.	
54.	Author unknown. (2002). "Dalbavanci <a href="http://www.versicor.com/products/da">http://www.versicor.com/products/da</a>		ust 27, 2002, one page.	
55.	Author unknown. (2002). "Treatment I Intravenous Catheter Cases," www.bio	Hope for Bloodstream Infections		
56.	Barna, J.C.J. and Williams, D.H. (1984) Antibiotics of the Vancomycin Group,	4). "The Structure and Mode of A" Ann. Rev. Microbiol. 38:339-3	Action of Glycopeptide 57.	
57.	Biavasco, F. et al. (2000). "Glycopeptide Susceptibility Profiles of Staphylococcus Haemolyticus Bloodstream Isolates," Antimicrobial Agents and Chemotherapy 44(11): 3122-3126.			
58.	Campbell, K.C.M. et al. (2003). "Audiologic Monitoring for Potential Ototoxicity in a Phase I Clinical Trial of a New Glycopeptide Antibiotic," J. Amer. Acad. Audiology. 14(3):157-168.			
59.				
EXAMINER:		DATE CONSIDERED:		
EXAMINER: Initi	al if citation considered, whether or not the citation of considered. Include a copy of this form with no	on conforms with MPEP 609. Draw a li ext communication to applicant.	ine through the citation if not in	

Form P1O-1449		Docket No. 892,280-147	Application No.: Not Yet Assigned	
	TION DISCLOSURE CITATION N AN APPLICATION	Applicant: CAVALERI et al.		
(	Use several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned	
		Mailing Date: April 16, 2004		
60.	Cavaleri, M. et al. (2002). "Protein Bi Microcalorimetry," 42nd ICAAC Abst. A-1385, pg. 18.			
61.	Cavaleri, M. et al. (2002). "Protein Binding of Dalbavancin Using Isothermal Titration Microcalorimetry," 42nd ICAAC, San Diego, CA, September 27-30, 2002. <u>Poster No. A-1385</u> , one page.			
62.	Chaix, C. et al. (1999). "Control of En 282(18):1745-1751.	demic Methicillin-Resistant Sta	phylococcus Aureus," JAMA	
63.	Crowe, M. et al. (1998). "Bacteraemia Nottingham, UK, 1985-1996," Eur. J.	in the Adult Intensive Care Unit Microbiol. Infect. Dis. 17: 377-3	of a Teaching Hospital in 84.	
64.	Darouiche, R.O. and Mansouri, D.M. (Date Unknown). "Dalbavancin Versus Vancomycin for Prevention of Staphylococcus aureus Colonization of Devices in an Animal Model," <u>Poster #17</u> one page.			
65.	Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," Abstracts of the IDSA 40th Annual Meeting, October 24 - 27, 2002. Abstract No. 52, pg. 53.			
66.	Dorr, M.B. et al. (2002). "Rationale for Glycopeptide," Abstracts of the IDSA one page.	or Once Weekly Dosing of Dalba 40th Annual Meeting, October 2	avancin, a New Semisynthetic 4 - 27, 2002. Poster No. 52,	
67.	Dowell, J. et al. (2003). "Dalbavancin Renal Impairment," <i>ECCMID</i> : <i>Clinica</i> 9(Supp. 1), p. 291.	Dosage Adjustments Not Requil Microbiology and Infection, A	red for Patients with Mild bstract No. P1224. Vol.	
68.	Dowell, J. et al. (2003). "Dalbavancin Renal Impairment," ECCMID: Clinical	Dosage Adjustments Not Requi	red for Patients with Mild oster No. P1224, one page.	
69.	Dowell, J.A. et al. (2002). "The Pharm Subjects," 42 ICAAC Abstracts, San D 18.	ncokinetics and Renal Excretion Diego, CA, September 27-30, 20	of Dalbavancin in Healthy 02. Abstract No. A-1386, pg	
70.	Dowell, J.A. et al. (2002). "The Pharm Subjects," 42 ICAAC, San Diego, CA,			
71.	71. Dowell, J.A. et al. (2003). "Dalbavancin (DAL) Pharmacokinetics (PK) in Subjects With Mild Moderate Hepatic Impairment (HI)," 43rd. Annual ICAAC, Chicago, IL, September 14-17, 200 Poster #A-19, one page.			
72.	Ednie, L. et al. (2003). "Antistaphylococcal Activity of Dalbavancin Compared to Those of Six Other Agents," 43rd. Annual ICAAC, Chicago, IL, September 14-17, 2003, Poster #C1-1631, one page.			
73.	Fieser, L.F. and Fieser, M. (1967). Reagents for Organic Synthesis John Wiley and Sons, Inc. pp. 128-130.			
EXAMINER:		DATE CONSIDERED:	·	
	tial if citation considered, whether or not the citation		ne through the citation if not in	

PTO/SB/ 08 (2-92)

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a	Ise several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned	
		Mailing Date: April 16, 2004		
74.	Fridkin, S.K. et al. (2003). "Epidemiological and Microbiological Characterization of Infections Caused by Staphylococcus Aureus with Reduced Susceptibility to Vancomycin, United States, 1997-2001," Clinical Infectious Diseases 2003 36: 429-439.			
75.	Ge, M. et al. (1999). "Vancomycin De Binding D-Ala-D-Ala," Science 284:50		can Biosynthesis Without	
76.	Goldstein, B.P. et al. (1994). "Compar the Glycopeptide Antibiotic A40926 (I October 4-7, 1994 Abstract No. F142	MDL 62,476)," Abstracts of the		
77.	Goldstein, D. (May 10, 2001). "Versicor, Inc. Will Host Conference Call to Discuss Advanced Clinical Development Programs For Lead Antifungal and Antibiotic Products." Press Release, two pages.			
78.	Goldstein, D. and Halsey, K. (Novemb Dalbavancin As The First Once-Week			
79.	Goldstein, D. and Halsey, K. (December 17, 2001). "Versicor Announces Data Demonstrating Tolerability of Anidulafungin at Higher Doses." Press Release, three pages.			
80.	Goldstein, D. and Halsey, K. (March 12, 2002). "Versicor Announces Start of Phase II Study of Once-Weekly Dalbavancin for Bloodstream Infections." Press Release, three pages.			
81.	Goldstein, D. and Halsey, K. (May 21, Once-Weekly Dalbavancin for Skin an			
82.	Goldstein, D. et al. (May 22, 2001). "Glycopeptide Antibiotic." Press Release	Versicor Begins Phase II Trial or se, three pages.	f Dalbavancin, Its Noval	
83.	Goldstein, D. et al. (December 17, 200 Dalbavancin, Demonstrating Feasabili			
84.	Goldstein, D. et al. (September 5, 200 Dalbavancin For Skin and Soft Tissue			
85.	Goldstein, D. et al. (September 19, 20 Annual ICAAC Meeting Next Week."	02). "Versicor Announces 24 Al Press Release, three pages.	ostracts to be Presented at	
86.	Goldstein, D. et al. (October 23, 2002) Advanced Product Candidates at IDSA			
87.	Goldstein, D. et al. (December 17, 2002). "Versicor Begins Phase III Trials of Dalbavancin for Skin and Soft Tissue Infections." Press Release, three pages.			
88.	Goldstein, E.J.C. and Citron, D.M. (2002). "In Vitro Activities of Dalbavancin and Nine Comparator Agents against Fastidious and Anaerobic Gram-Positive Species," 42nd ICAAC Abstracts, San Diego, CA, September 27 - 30, 2002. Abstract No. E-1454, pg. 163.			
EXAMINER:		DATE CONSIDERED:		
EXAMINER: Init	ial if citation considered, whether or not the citation	on conforms with MPEP 600 Draw all	ing through the citation if not i-	

conformance and not considered. Include a copy of this form with next communication to applicant.

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(	Use several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned	
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89.	Goldstein, E.J.C. et al. (2003). "In Vi against Anaerobic Gram-Positive Spect 47(6): 1968-1971.	tro Activities of Dalbavancin ancies and Corynebacteria," Antim	d Nine Comparator Agents icrob. Agents and Chemother.	
90.	Greene, T. W. (1981). Protective Ground (Table of Contents Only.)	ups in Organic Synthesis John W	Viley and Sons, Inc. pp. ix-x	
91.	Griffin, J.H. (2003). "Multivalent Drug Vancomycin Dimers," <i>JACS</i> 125:6517		Analysis of an Array of	
92.	Hackbarth, C.J. et al. (1999). "In Vitro aureus and Staphylococcus epidermidi Abstract No. 1283, pg. 332.	o Activity of the Glycopeptide Es," 39th Annual ICAAC, San Fra	BI 397 Against Staphylococcus incisco, CA. September 1999.	
93.	Hackbarth, C.J. et al. (1999). "In Vitro Activity of the Glycopeptide BI 397 Against Staphylococca aureus and Staphylococcus epidermidis," 39th Annual ICAAC, San Francisco, CA. September 199 Poster No. 1283, one page.			
94.	Hackbarth, C.J. et al. (2001). "Antibacterial Activity of V-Glycopeptide (VER001), A Semi-Synthetic Glycopeptide, Against Staphylococcus aureus," ASM, May 2001. Abstract No. A-4.			
95.	Hackbarth, C.J. et al. (2001). "Antibacterial Activity of Dalbavancin (VER-001), A Semi-Synthet Glycopeptide, Against Staphylococcus aureus," ASM, May 2001. Poster No. A-4, one page.			
96.	Harding, I. et al. (2000). "Teicoplanin Between Pre-Dose Serum Concentration	Therapy for Staphylococcus Aurons and Outcome," JACS 45:835	eus Septicaemia: Relationship -841.	
97.	Heiselman, D. (1994). "Nosocomial B 272(23):1819-1820.	loodstream Infections in the Crit	ically Ill," <i>JAMA</i>	
98.	Hiramatsu, K. et al. (1997). "Dissemin Aureus Heterogeneously Resistant to V			
99.	Jabes, D. et al. (2001). "Efficacy of a Linezolid (LN) Doses against Penicilli Model in the Immunocompetent Rat (I 2001. Abstract No. B-989, p. 54.	n-Resistant Pneumococci (PRSF	) in a Lobar Pneumonia (LP)	
100.	Jabes, D. et al. (December, 2000). "In vitro and in vivo Bactericidal Activity of the New Glycopeptide BI 397 and Correlations with Drug Concentrations," BioSearch Italia, S.P.A., San Antonio, December 2000, Poster No. F5, one page.			
101.	Jabes, D. et al. (2001). "Efficacy of a Single Dalbavancin (DA) Dose Compared with Multiple Vancomcin (VA) Doses against MRSA in the Rat Pouch Model of Infection," 41st. ICAAC Abstracts Chicago, IL. September 22 - 25, 2001. Abstract No. B-1654, pg. 68.			
102.	Jabes, D. et al. (2001). "Efficacy of a Single Dalbavancin (DA) Dose Compared with Multiple Vancomcin (VA) Doses against MRSA in the Rat Pouch Model of Infection," 41st. ICAAC, Chicago, IL. December, 2001. Poster No. B-1654, one page.			
EXAMINER:		DATE CONSIDERED:		
EXAMINER: Init	rial if citation considered, whether or not the citation to considered. Include a copy of this form with n	on conforms with MPEP 609. Draw a liext communication to applicant.	ine through the citation if not in	

Form PTO-1	449		Docket No. 892,280-147	Application No.: Not Yet Assigned
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	(Us	e several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned
			Mailing Date: April 16, 2004	
	<del></del> -			
1	03.	Jabes, D. et al. (2003). "Efficacy of Da Rat Granuloma Pouch Model of Staphy Italy Poster No. P1, one page.	lbavancin Compared with Vanc ylococcal Infection," Symposium	omycin and Linezolid in the non Surgical Infections, Como,
1	04.	Jain, R.K. (2003). "D-Ala-D-Lac Bindin Dimers Against Vancomycin Resistant		
1	05.	Jones, R. N. et al. (2001). "Activity and Spectrum Evaluation of Dalbavancin (V-Glycopeptide an BI397), A Novel "Glycopeptide" Class Antimicrobial," 41st ICAAC Abstracts, Chicago, IL. September 22-25, 2001, Abstract No. 2276, pg. 200.		
1	06.	Jones, R. N. et al. (2001). "Activity and Spectrum Evaluation of Dalbavancin (V-Glycopeptide and BI397), A Novel "Glycopeptide" Class Antimicrobial," 41st ICAAC Chicago, IL. December, 2001 Poster No. 2276, one page.		
1	07.	Jones, R.N. et al. (2001). "In Vitro Evaluation of BI 397, a Novel Glycopeptide Antimicrobial Ager Journal of Chemotherapy 13(3):244-254.		
1	08.	8. Jordan, M.K. et al. (2002). "A Novel Use of Optimal Sampling Theory (OST) During Drug Development," <i>American Society of Clinical Pharmacology &amp; Therapeutics</i> , Atlanta, GA, March 2002. <u>Poster</u> , one page.		
1	09.	Kenny, M.T. et al. (1995). "In Vitro Ac 63,246," Antimicrobial Agents and Ch	ctivity of the Semisynthetic Glycemotherapy 39(7):1589-1590.	copeptide Amide MDL
1	10.	Lefort, A. et al. (2002). "Activity of Dadue to Methicillin-Resistant Staphylocon Glycopeptides (GISA)," 42nd ICAAC Anno. B-278, page 33.	occus aureus (MRSA) Susceptib	ole or Intermediate to
1	11.	Leighton, A. et al. (2001). "Dalbavanc Intravenous Safety, Pharmacokinetic S IL September 22-25, 2001. Abstract No.	tudy in Healthy Volunteers," 41	
1	12.	Leighton, A. et al. (2001). "Dalbavanc Intravenous Safety, Pharmacokinetic S December, 2001. <u>Poster No. 951</u> , one	tudy in Healthy Volunteers," 41	Dose Placebo Controlled st ICAAC, Chicago, IL
1	13.	Leighton, A. et al. (2001). "Stringent Audiology Assessments in a Healthy Volunteer Study with the Glycopeptide Dalbavancin," 41st ICAAC Abstracts, Chicago, IL, September 22 - 25, 2001. Abstract No. A-2192, pg. 37.		
1	14.	Leighton, A. et al. (2001). "Stringent Audiology Assessments in a Healthy Volunteer Study with the Glycopeptide Dalbavancin," 41st ICAAC, Chicago, IL, December, 2001. Poster No. A-2192, one page.		
1	15.	Lopez, S. et al. (2003). "In Vitro Susceptibility and Population Analysis of Staphylococci After Serial Passage at Sub-MIC Levels of Dalbavancin and Other Glycopeptides," Clinical Microbiology and Infection, 9(Supp. 1), pg. 375 Abstract No. P1539.		
EXAMINE	R:		DATE CONSIDERED:	
EXAMINER conformance	: Initia	I if citation considered, whether or not the citation to considered. Include a copy of this form with ne	n conforms with MPEP 609. Draw a liext communication to applicant.	ne through the citation if not in

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. "	lse several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned	
		Malling Date: April 16, 2004		
	Y			
116.	Lopez, S. et al. (2003). "In Vitro Susce Passage at Sub-MIC Levels of Dalbave No. P1539, one page.			
117.	Lyght, C.E. et al. eds. (1966). The Mer & Dohme Research Laboratories pp. 7	rck Manual of Diagnosis & Ther 799-862.	apy 11th Edition, Merck Sharp	
118.	Malabarba, A. and Ciabatti, R. (2001) 8(14):1759-1773.	. "Glycopeptide Derivatives," C	urrent Medicinal Chemistry	
119.	Malabarba, A. and Donadio, S. (1999) 24(8):839-846.	. "BI-397: Glycopeptide Antibio	tic," Drugs of the Future	
120.	Malabarba, A. et al. (1987). "Synthesis and Biological Activity of Some Esters of the N-Acetylglucosaminyl Aglycone and of the Aglycone of Teicoplanin," The Journal of Antibiotics 40(11):1572-1587.			
121.	Malabarba, A. et al. (1995). "New Semisynthetic Glycopeptides MDL 63,246 and MDL 63,042, and Other Amide Derivatives of Antibiotic A-40,926 Active Against Highly Glycopeptide-Resistant VanA Enterococci," <i>Journal of Antibiotics</i> 48(8):869-883.			
122.	Malabarba, A. et al. (1997). "Structural Modifications of Glycopeptide Antibiotics," <i>Medicinal Research Reviews</i> 17(1):69-137.			
123.	Malabarba, A. et al. (1998). "BI 397: A New Developmental Semisynthetic Glycopeptide Antibiotic," Abstracts of the 38th ICAAC September 24 - 27, 1998, San Diego, CA Abstract No. F107 pg. 259.			
124.	Mammen, M. et al. (1998). "Polyvalen and Use of Multivalent Ligands and In			
125.	McGovern, S.L. et al. (2002). "A Com Virtual and High-Throughput Screening			
126.	McOmie, J.F.W. ed. (1973). Protective p. xi (Table of Contents Only.)	Groups in Organic Chemistry	Plenum Press: New York, NY	
127.	Neu, H.C. (1992). "The Crisis in Antib	piotic Resistance," Science 257:	1064-1073.	
128.	Newell, K.A. et al. (1998). "Incidence Enterococcus Following Orthotopic Li			
129.	9. Nicolaou, K.C. et al. (1999). "Chemistry, Biology, and Medicine of the Glycopeptide Antibiotics,"  Angew. Chem. Int. Ed. 38:2096-2152.			
130.	Nicolaou, K.C. et al. (2000). "Target-Accelerated Combinatorial Synthesis and Discovery of Highly Potent Antibiotics Effective Against Vancomycin-Resistant Bacteria," <i>Angew. Chem. Int. Ed.</i> 39(21):3823-3828.			
EXAMINER:		DATE CONSIDERED:		
	EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.			

Form PTO-1449		Docket No. 892,280-147	Application No.: Not Yet Assigned		
	ION DISCLOSURE CITATION AN APPLICATION	Applicant: CAVALERI et al.			
(L	/se several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned		
		Mailing Date: April 16, 2004			
<del></del> -					
131.		esis and Biological Evaluation of Vancomycin Dimers with a-Resistant Bacteria: Target-Accelerated Combinatorial 4-3843.			
132.	Nisbet, L.J. et al. (1986). "Discovery, Comparative Antibacterial Activity and Structure Elucidation of AAJ-271, a Novel Group of Glycopeptides," 26th Annual ICAAC, New Orleans, LA October, 1986, Abstract No. 226, pg. 137.				
133.	Ochalski, T.J.and Zuk, J. (1998). "Phot Quantum Well Laser Structures," Acta		/GaAs/AlGaAs Single		
134.	Ōmura, S. et al. (1984). "Effect of Ama Biosynthesis of Protylonolide, a Precur 37(5):494-502.				
135.	Omura, S. et al. (1984). "Bioconversion and Biosynthesis of 16-Membered Macrolide Antibiotics. XXIX: Effect of Ammonium Ion, Inorganic Phosphate and Amino Acids on the Biosynthesis of Protylonolide, a Precursor of Tylosin Aglycon," (1984). Chemical Abstracts Abstract No. 51459t. 101:318.				
136.	Pavlov, A.Y. and Preobrazhenskaya, M.N. (1998). "Synthesis and Antibacterial Activity of Derivatives of the Glycopeptide Antibiotic A-40926 N-Alkylated at the Aminoglucuronyl Moiety," <i>Journal of Antibiotics</i> 51(5):525-527.				
137.	Popieniek, P.H. and Pratt, R.F. (1987). Antibiotics of the Vancomycin Class,"				
138.	Printsevskaya, S.S. et al. (2002). "Synt Glycopeptide Antibiotic Eremomycin a Glycopeptide-Sensitive and -Resistant	and Des-(N-methyl-D-leucyl)ere	momycin Against		
139.	Printsevskaya, S.S. et al. (2003). "Role of Hydrophobic Derivatives of Glycop				
140.	Rao, J. and Whitesides, G.M. (1997). "Dimeric L-Lys-D-Ala-D-Ala," J. Am. C	"Tight Binding of a Dimeric Derivative of Vancomycin with Chem. Soc. 119:10286-10290.			
141.	Rao, J. et al. (1999). "Binding of a Dim Solution and at a Surface," Chemistry of		Derivative of Vancomycin to L-Lys-D-Ala-D-Lactate in a ology 6:353-359.		
142.	Rao, J. et al. (1999). "Using Surface Pl Dimer to Self-Assembled Monolayers				
143.	Richards, M.J. et al. (1999). "Nosocon States," Crit. Care. Med. 27(5): 887-8		sive Care Units in the United		
144.	144. Riva, E. et al. (1987). "Column Purification and HPLC Determination of Teicoplanin and A409 Chromatographia 24:295-301.				
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EXAMINER:		DATE CONSIDERED:			
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rom P10-1449		Docket No. 892,280-147	Application No.: Not Yet Assigned	
)	ION DISCLOSURE CITATION AN APPLICATION	Applicant: CAVALERI et al.		
ıυ	lse several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned	
		Mailing Date: April 16, 2004		
145.	Romano, G. et al. (2003). "In Vitro An Compounds Against Recent Clinical Is Poster P3, one page.			
146.	Roy, R.S. et al. (2001). "Direct Interaction of a Vancomycin Derivative with Bacterial Enzymes Involved in Cell Wall Biosynthesis," <i>Chemistry &amp; Biology</i> 8/11:1095-1106.			
147.	Schäfer, M. et al. (1996). "The Moleci Aglycone," <i>Helvetica Chimic Acta</i> 79:		Glycopeptide A-40926	
148.	Schwyzer, R. et al. (1955). "Über Akti abstract pg. 79.)	vierte Ester," Helv. Chim. Acta.	38(7/8):69-79. (English	
149.	Seltzer, E. et al. (2003). "Dalbavancin: Phase 2 Demonstration of Efficacy of a Novel, Weekly Dosing Regimen in Skin and Soft Tissue Infections," <i>ECCMID</i> , May 2003, Abstract No. O143, p. 22.			
150.	Selva, E. et al. (1988). "A40926 Aglycone and Pseudoaglycones: Preparation and Biological Activity," <i>The Journal of Antibiotics</i> 41(9):1243-1252.			
151.	Shopsin, B. et al. (2000). "Prevalence of Methicillin-Resistant and Methicillin-Susceptible Staphylococcus Aureus in the Community," The Journal of Infectious Diseases 182:359-362.			
152.	Sieradzki, K. et al. (1998). "Decreased Susceptibilities to Teicoplanin and Vancomycin Among Coagulase-Negative Methicillin-Resistant Clinical Isolates of Staphylococci," <i>Antimicrobial Agents and Chemotherapy</i> 42(1): 100-107.			
153.	Sieradzki, K. et al. (1999). "The Devel Methicillin-Resistant Staphylococcus			
154.	Staroske, T. and Williams, D.H. (1998) Vancomycin," <i>Tetrahedron Letters</i> 39		to-Tail Dimers of	
155.		e Assessment of Dalbavancin Activity and Spectrum (2002)," otember 14-17, 2003, Poster #F-2107, one page.		
156.	Stogniew, M. et al. (2003). "Pharmaco Completely Eliminated with Dual Rou			
157.	157. Stogniew, M. et al. (2003). "Attributes of Dalbavancin: Well Distributed, Weekly Dosing, and Completely Eliminated," <i>ECCMID Clinical Microbiology and Infection</i> , Abstract No. P1225, 9(Supp 1) pg. 291.			
158.	Sundram, U.N. and Griffin, J.H. (1996). "Novel Vancomycin Dimers with Activity Against Vancomycin-Resistant Enterococci," J. Am. Chem. Soc. 118:13107-13108.			
159.	Süssmuth, R. D. (2002). "Vancomycin Resistance: Small Molecule Approaches Targeting the Bacterial Cell Wall Biosynthesis," <i>ChemBioChem</i> 3:295-298.			
160.	Tenover, F.C. et al. (2001). "Increasin Staphlococcus Aureus," Emerging Infe		d Other Glycopeptides in	
EXAMINER:		DATE CONSIDERED:		
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.			line through the citation if not in	

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Form PTO-1449		Docket No. 892,280-147	Application No.: Not Yet Assigned
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rv	se several sheets if necessary)	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned
		Mailing Date: April 16, 2004	
	<u> </u>		
161.	Verhoef, J. (1993). "Prevention of Infe 17(S2):S359-S367.	ections in the Neutropenic Patien	t," Clinical Infectious Diseases
162.	Walsh, C. (2000). "Molecular Mechanisms That Confer Antibacterial Drug Resistance," <i>Nature</i> 406:775-781.		
163.	Walsh, C.T. et al. (1996). "Bacterial Resistance to Vancomycin: Five Genes and One Missing Hydrogen Bond Tell the Story," <i>Chemistry &amp; Biology</i> 3:21-28.		
164.	White, R.J. et al. (2000). "V-Glycopeptide: Phase 1 Single and Multiple-Dose Placebo Controlled Intravenous Safety, Pharmacokinetic, and Pharmacodynamic Study in Healthy Subjects," 40th ICAAC, Toronto, CN. September 17 - 20, 2000, Poster No. 2196, one page.		
165.	White, R.J. et al. (2000). "V-Glycopeptide: Phase 1 Single and Multiple-Dose Placebo Controlled Intravenous Safety, Pharmacokinetic, and Pharmacodynamic Study in Healthy Subjects," 40th ICAAC Abstracts, Toronto, CN. September 17-20, 2000, Abstract No. 2196, one page.		
166.	Williams, D.H. et al. (1998). "An Analysis of the Origins of a Cooperative Binding Energy of Dimerization," <i>Science</i> 280:711-714.		
167.	Xu, R. et al. (1999). "Combinatorial Library Approach for the Identification of Synthetic Receptors Targeting Vancomycin-Resistant Bacteria," J. Am. Chem. Soc. 121:4898-4899.		
168.			

EXAMINER:	,	DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.